

## Corporate Medical Policy

### Electrocardiographic Body Surface Mapping

<b>File Name:</b>	eletrocardiographic_body_surface_mapping
<b>Origination:</b>	6/2009
<b>Last CAP Review:</b>	10/2011
<b>Next CAP Review:</b>	10/2012
<b>Last Review:</b>	10/2011

#### Description of Procedure or Service

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Electrocardiographic body surface mapping (BSM) is an electrocardiographic (ECG) technique that uses multiple (generally 80 or more) electrocardiography leads to detect cardiac electrical activity. It is suggested that the use of multiple leads may result in improved diagnostic accuracy compared to the standard 12-lead ECG. One potential use of this device is in the early evaluation of occult ischemia in patients who do not meet the current definition of ST-elevation myocardial infarction (STEMI). Another potential use is a more rapid stratification of low-risk chest pain patients who present to the emergency department.

##### Background

Electrocardiographic body surface mapping (BSM) consists of an 80-lead disposable electrode array in the form of a vest that includes a conducting gel that is applied to the patient's chest and back. The vest can be applied in less than 5 minutes. This system displays clinical data in three forms; a colorimetric 3-D torso image, an 80-lead single beat view, and the 12-lead ECG. The colorimetric torso images are said to allow the practitioner to rapidly scan the heart for significant abnormalities.

Currently, in patients presenting to the emergency department with symptoms suggestive of myocardial ischemia, a standard 12-lead ECG is obtained. In the presence of ST segment elevation on the ECG, personnel are activated to respond in a timely manner to open a presumed coronary artery occlusion, either by mechanical means through balloon angioplasty, or medically through intravenous thrombolytic drugs. The 12-lead ECG has a specificity of 94%, leading to relatively few erroneous interventions. However, the sensitivity is about 50%. These patients may be further stratified by scoring systems and time-sensitive cardiac enzymes, which may require up to 24 hours of monitored observation. BSM is being considered as a method to assist in the rapid identification of patients who would benefit from earlier coronary artery intervention than currently achieved utilizing current standard of care. The negative predictive value of the test, which has the potential to identify patients who do not require further evaluation with serial cardiac enzymes and clinical observation, is not currently receiving attention as a research topic.

##### Regulatory Status

In March 2002, the device "PRIME ECG® (Verathon, Bothell, W A) was cleared for marketing by the FDA through the 510(k) process. The FDA determined that the device was substantially equivalent to existing devices for use in recording of ECG signals on the body surface.

**\*\*\*Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

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## Policy

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**BCBSNC does not cover electrocardiographic body surface mapping. It is considered investigational. BCBSNC does not provide coverage for investigational services or procedures.**

## Benefits Application

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This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

## When Electrocardiographic Body Surface Mapping is covered

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Not Applicable

## When Electrocardiographic Body Surface Mapping is not covered

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Electrocardiographic body surface mapping is considered investigational for the diagnosis or management of cardiac disorders including acute coronary syndrome.

## Policy Guidelines

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A number of studies have examined the association between electrocardiographic body surface mapping and acute myocardial infarction, but no prospective trials using body surface mapping to guide treatment have been conducted.

The American College of Cardiology guidelines for electrocardiography standardization and interpretation recognize that the studies of body surface maps from large electrode arrays have provided useful information about localization of ECG information on the thorax. However, the guidelines state that the complexity of electrocardiographic body surface maps precludes their use as a substitute for the standard 12-lead ECG for routine recording purposes. The clinical utility of the body surface mapping technique, both in terms of benefits and risks and burdens, has not been demonstrated.

In 2010, the Agency for Healthcare Research and Quality (AHRQ) published a technology assessment on the diagnostic utility of ECG-based signal analysis technologies for patients at low to intermediate risk of coronary artery disease (CAD). The AHRQ assessment found: "There is currently little available evidence that pertains to the utility of ECG-based signal analysis technologies as a diagnostic test among patients at low to intermediate risk of CAD who present in the outpatient setting with the chief complaint of chest pain." The assessment concluded, "Further research is needed to better characterize the performance characteristics of these devices to determine in what circumstances, if any, these devices might precede, replace, or add to the standard ECG for the diagnosis of CAD among patients who present with chest pain in the outpatient setting."

## Billing/Coding/Physician Documentation Information

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbsnc.com](http://www.bcbsnc.com). They are listed in

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the Category Search on the Medical Policy search page.

*Applicable service codes: 0178T, 0179T, 0180T*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

## Scientific Background and Reference Sources

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BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.23, 7/10/08

Food and Drug Administration (FDA) 501(k) Summary K082312 for Prime ECG. Retrieved on September 15, 2010 from [http://www.accessdata.fda.gov/cdrh\\_docs/pdf8/K082312.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf8/K082312.pdf)

Kligfield P, Gettes LS, Bailey JJ et al. Recommendations for the standardization and interpretation of the electrocardiogram: part I: the electrocardiogram and its technology a scientific statement from the American Heart Association Electrocardiography and Arrhythmias Committee, Council on Clinical Cardiology; the American College of Cardiology Foundation; and the Heart Rhythm Society endorsed by the International Society for Computerized Electrocardiology. *J Am Coll Cardiol* 2007; 49(10):1109-27.

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.23, 8/12/10

Specialty Matched Consultant Advisory Panel review 10/2010

Coeytaux RR WJ, Chung E, Gharacholou M. Technology Assessment. ECG-based signal analysis technologies. Prepared for the Agency for Healthcare Research and Quality (AHRQ) by the Duke Evidence-based Practice Center. 2010. Retrieved on September 15, 2011 from <http://www.cms.gov/determinationprocess/downloads/id73TA.pdf>

O'Neil BJ, Hoekstra J, Pride YB et al. Incremental benefit of 80-lead electrocardiogram body surface mapping over the 12-lead electrocardiogram in the detection of acute coronary syndromes in patients without ST-elevation myocardial infarction: Results from the Optimal Cardiovascular Diagnostic Evaluation Enabling Faster Treatment of Myocardial Infarction (OCCULT MI) trial. *Acad Emerg Med* 2010; 17(9):932-9. Retrieved on September 15, 2011 from <http://onlinelibrary.wiley.com/doi/10.1111/j.1553-2712.2010.00848.x/pdf>

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.02.12, 8/11/11

Specialty Matched Consultant Advisory Panel review 10/2011

## Policy Implementation/Update Information

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8/31/09 New policy issued. Electrocardiographic body surface mapping is considered investigational for the diagnosis or management of cardiac disorders including acute coronary syndrome. (adn)

12/7/09 Specialty Matched Consultant Advisory Panel review meeting 10/30/09. No change to policy statement. (adn)

6/22/10 Policy Number(s) removed (amw)

11/23/10 Specialty Matched Consultant Advisory Panel review 10/2010. Description section

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revised. Policy Guidelines updated. References updated. (mco)

11/8/11 References updated. Policy Guidelines updated. Specialty Matched Consultant Advisory Panel review 10/2011. No changes to Policy Statements. (mco)

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.